DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

June 29, 2007

Marc S. Ullman, Esq.
Ullman, Shapiro & Ullman, LLP
299 Broadway, Suite 1700
New York, New York 10007

Dear Mr. Ullman:

I am writing in regard to the disposition of certain quantities of wheat gluten, owned by your client, ChemNutra, Inc. (ChemNutra) and held at multiple facilities throughout the country.[1]

FDA's inspections, analysis, and records show that ChemNutra's wheat gluten contains melamine and/or melamine analogs, causing the product to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§ 301 et seq.

As you may know, representatives from several FDA District Offices, including Kansas City, Philadelphia, and New Jersey, have been involved in continued discussions with ChemNutra regarding its adulterated wheat gluten. FDA acknowledges that ChemNutra has cooperated in the recall of the product, and that presently there is a large quantity on voluntary hold at multiple facilities throughout the United States. ChemNutra previously agreed to voluntarily destroy this recalled product, however, you have stated that ChemNutra is now unable to destroy the product due to a May 22, 2007 Order from United States District Judge George H. King in the Central District of California in Townsend v. Menu Foods, et. al.

FDA continues to be concerned about the potential public health risk, especially to animals, associated with the retention of approximately 430 metric tons of adulterated wheat gluten in storage in various parts of the country. Until the product is destroyed, there is a risk of reintroduction into interstate commerce, whether intentional or not, and/or a risk of export.

FDA understands that your client has assured you that it will not move the product, nor have anyone move the product on its behalf. However, in light of the large quantity of product in storage, the potentially lengthy storage time, and a lack of uniform control over access to the wheat gluten and relevant security issues, FDA continues to be concerned that some of the product may find its way back to the market and be used commercially.

[1] Information provided to FDA by ChemNutra indicates that, as of June 5, 2007, ChemNutra had approximately 430 metric tons (MT) of wheat gluten at three locations in the United States: approximately 278 MT at MoKan Container Service, Inc. in Kansas City, Missouri; 72 MT at Steven Shannon Warehouse in Bloomsburg, Pennsylvania; and 80 MT at Standard Warehouse and Distribution Co., Ltd. in Pennsauken, New Jersey.

Attachment B
to Miller Decl.

FDA understands that a certain amount of the adulterated product may need to be retained for use in ongoing or potential litigation. However, the volume of product currently on hand at the multiple domestic facilities would appear to be in excess of that typically necessary for evidentiary purposes. FDA requests that your client consider the option of retaining a representative sample of ChemNutra's adulterated wheat gluten, and destroying the remainder under FDA supervision. Of course, the Agency urges you to seek whatever relief is appropriate from the Court in your underlying litigation to accomplish this.

If you have any questions or concerns relating to the contents of this letter, please feel free to contact me at 240-632-6800.

Sincerely,

David K. Elder
Director, Office of Enforcement
Office of Regulatory Affairs
U.S. Food and Drug Administration